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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,934	05/03/2000	ANDREAS STEINMEYER	SCH1747	6707

7590

09/09/2004

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT PAPER NUMBER

1616

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/509,934

Applicant(s)

STEINMEYER ET AL.

Examiner

Sabiha Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,6,8-11 and 14-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-3,5,6,8-11 and 14-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

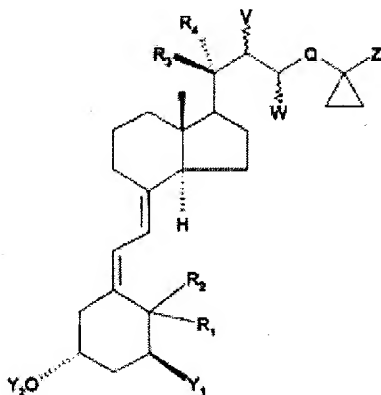
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Non-Final Office Action

Claims 1-3, 5, 6, 8-11, and 14-48 are pending. No claim is allowed. Rejections are maintained.

Amendments are entered. This application is a 371 of PCT/EP98/06159 filed on 9/29/1998.

Instant claims are drawn to vitamin D compounds of formula I:



Applicant is requested to give the definition of Z¹ in claim 6.

Response to Arguments

This is in response to the Remarks filed on May 24, 2004.

Amendments

Amendments have been entered.

Applicant is requested to show where the support is (in disclaimer language) for Claim 1's "wherein Q is not CHOH."

Restriction

Applicants argue that the withdrawal of the method of use claims 8-11 and 15-18 is in violation of PCT Rule 13. Examiner respectfully disagrees. PCT Rule 13 states:

“13.1 Requirement

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (“requirement of unity of invention”).

13.2 Circumstances in Which the Requirement of Unity of Invention Is to Be Considered Fulfilled

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

13.3 Determination of Unity of Invention Not Affected Manner of Claiming

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

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13.4 Dependent Claims

Subject to Rule 13.1, it shall be permitted to include in the same international application a reasonable number of dependent claims, claiming specific forms of the invention claimed in an independent claim, even where the features of any dependent claim could be considered as constituting in themselves an invention.”

Examiner would like to draw Applicants’ attention to Rule 13.2, which states, “...among those inventions involving one or more of the same or corresponding special technical features.” The claims need to be restricted because they do not have one or more of the same corresponding technical features. Rule 13.2 goes on to state, “The expression ‘special technical features’ shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.” The presently claimed inventions do not make a contribution, when considered as a whole, over the prior art. The claims do not relate to a single general inventive step because the definitions of the substituents attached to vitamin D-ring system are different.

Examiner would like to direct the Applicants’ attention to PCT Rule 13.4 (cited above), which states: “Subject to Rule 13.1, it shall be permitted to include in the same international application a *reasonable number* of dependent claims...”

Restrictions/Elections

This application contains claims 1-3, 5, 6, 8-11, and 14-48 lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art.

- I. Claims 1-3, 5, 6, 14, 20-28 and 30-48, drawn to vitamin D compounds compositions and their process of making. When R1 and R2 is H, V and W together present a double bond; R3 and R4 represent a H or an alkyl group.
- II. Claims 1-3, 5, 6, 14, 20-28 and 30-48, drawn to compounds, compositions and their process of making when R1 and R2 is methylene, V and W together present a double bond, R3 and R4 represent a H or an alkyl group.
- III. Claim 8, drawn to method for treating...
- IV. Claim 9, drawn to method for treating...
- V. Claim 10 drawn to method for treating...

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- VI. Claim 11, drawn to method for treating...
- VII. Claim 19, drawn to specific compound, compositions and their process of making.
- VIII. Claim 29, drawn to method for preparing pharmaceutical composition.
- IX. Claim 15, drawn to a method for treating.
- X. Claim 16, drawn to a method for regulating hair growth.
- XI. Claim 17, drawn to a method of providing birth control to a male or female.
- XII. Claim 18, drawn to method of inducing an immuno-stimulant effect.
- XIII. Claims 1-3, 5, 6, 14, 20-28 and 30-48, drawn to compounds, compositions and their method of making when R1 and R2 are methylene, V and W together present a double bond, R3 and R4 represent other than H or an alkyl group.
- XIV. Claims 1-3, 5, 6, 14, 20-28 and 30-48 drawn to compounds, compositions and their method of making when R1 and R2 are H, V and W together present a double bond, R3 and R4 represent other than H or an alkyl group.

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XV. Claims 1-3, 5, 6, 14, 20-28 and 30-48 drawn to compounds, compositions and their method of making when R1 and R2 are H, V and W together present a double bond, R3 and R4 represent hydrogen or with quaternary carbon atom form a 3- to 7-membered, saturated or unsaturated carbocyclic ring.

XVI. Claims 1-3, 5, 6, 14, 20-28 and 30-48, drawn to compounds, compositions and their method of making when R1 and R2 are methylene, V and W together present a double bond, R3 and R4 represent hydrogen or with quaternary carbon atom form a 3- to 7-membered, saturated or unsaturated carbocyclic ring.

XVII. Claims 1-3, 5, 6, 14, 20-28 and 30-48, drawn to vitamin D compounds compositions and their process of making. When R1 and R2 is H, V and W together present a double bond; R3 and R4 represent hydrogen or with quaternary carbon atom form a 3- to 7-membered, saturated or unsaturated carbocyclic ring.

XVIII. Claims 1-3, 5, 6, 14, 20-28 and 30-48, drawn to compounds, compositions and their method of making when R1 and R2 is methylene, V and W together present a double bond, R3 and R4 represent hydrogen or with quaternary carbon atom form a 3- to 7-membered, saturated or unsaturated carbocyclic ring.

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XIX. Claims 1-3, 5, 6, 14, 20-28 and 30-48 drawn to compounds, compositions and their method of making when R1 and R2 are H, V and W together present a double bond, R3 and R4 represent hydrogen and chlorine and fluorine.

XX. Claims 1-3, 5, 6, 14, 20-28 and 30-48, drawn to compounds, compositions and their method of making when R1 and R2 are methylene, V and W together present a double bond, R3 and R4 represent hydrogen and chlorine and fluorine.

XXI. Claims 1-3, 5, 6, 14, 20-28 and 30-48, drawn to vitamin D compounds compositions and their process of making. When R1 and R2 is H, V and W together present a double bond; R3 and R4 represent hydrogen and chlorine and fluorine.

XXII. Claims 1-3, 5, 6, 14, 20-28 and 30-48, drawn to compounds, compositions and their method of making when R1 and R2 is methylene, V and W together present a double bond, R3 and R4 represent hydrogen and chlorine and fluorine.

XXIII. Claims 1-3, 5, 6, 14, 20-28 and 30-48 drawn to compounds, compositions and their method of making when R1 and R2 are H, V and W together present a double bond, R3 and R4 represent hydrogen and methylene.

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XXIV. Claims 1-3, 5, 6, 14, 20-28 and 30-48, drawn to compounds, compositions and their method of making when R1 and R2 are methylene, V and W together present a double bond, R3 and R4 represent hydrogen and methylene.

XXV. Claims 1-3, 5, 6, 14, 20-28 and 30-48, drawn to vitamin D compounds compositions and their process of making. When R1 and R2 is H, V and W together present a double bond; R3 and R4 represent hydrogen and methylene.

XXVI. Claims 1-3, 5, 6, 14, 20-28 and 30-48, drawn to compounds, compositions and their method of making when R1 and R2 is methylene, V and W together present a double bond, R3 and R4 represent hydrogen and methylene.

Method of use claims will be joined with the allowed compound in condition that that are no 112 issues (such as method for treating “cancer” or “precancerous conditions”) and are fully supported by the disclosure. The claims should be amended to advance the prosecution.

Reasons for Restriction/Election Requirement

The inventions are distinct, each from the other because of the following reasons:

The invention of group I, II and III-XV are drawn to structurally dissimilar compounds with different cores and their method of use. Compounds of group I are drawn to vitamin D compounds, their preparation and method of use whereas intermediate compounds of group X are epoxy dioxalane compounds. Similarly the methods of treatment of regulating hair growth

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are completely different from a method of providing birth control. All the methods as cited group are different and according to PCT rules represent lack of unity of invention.

These groups are separate inventions and are patentably distinct. A reference used to reject invention of group I will not be used to reject the invention of any other group. Similarly in vitamin D art compounds having 19-nor structure, R3 and R4 are H, or alkyl and having double bond in the side chain will be different from the compounds having a 19-methylene group and R3 and R4 other than H or alkyl. Similarly Z and Q are too broad in vitamin D art because a minor change in structure is very significant in this class of compounds.

Inventions (I, II, VII, VIII, and XIII- XXVI) and (III-VI and IX-XII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process of using the product as claimed can be practiced with another materially different product.

Accordingly, unity of invention is lacking and restriction of the invention in accordance with the rules of unity of invention is proper. Applicant is requested to elect a species from the elected group for search purposes. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventor ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Explanation for Another Restriction/Election Requirement

The Examiner does not understand why the Applicants choose to prolong the prosecution of this Application. In order to further the prosecution and simplify the issues, Applicants must elect a group according to the rules of PCT Rule 13.1 and 13.2, which is cited very clearly above, and in our previous Office Actions.

Applicants have been hindering the advancement of the prosecution of this application by refusing to elect a single invention, adding many new claims after almost every Office Action, and arguing that the addition of new claims and inventions is justified as well as arguing that the restriction/election requirement is incorrect.


Examiner requests the Applicants to elect a single invention and to stop adding new inventions in order to advance the prosecution of this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


SABIHA QAZI, PH.D
PRIMARY EXAMINER

Monday, September 6, 2004